care services to be offered under the M+C contract; or

- (ii) Federal waiver as described in subpart H of this part.
- (2) The authorized individual must describe thoroughly how the entity and M+C plan meet, or will meet, the requirements described in this part.
- (c) Responsibility for making determinations. HCFA is responsible for determining whether an entity qualifies as an M+C organization and whether proposed M+C plans meet the requirements of this part.
- (d) Resubmittal of application. An application that has been denied by HCFA may not be resubmitted for 4 months after the date of the notice from HCFA denying the application.
- (e) Disclosure of application information under the Freedom of Information Act. An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

§ 422.8 Evaluation and determination procedures.

- (a) Basis for evaluation and determination. (1) HCFA evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.
- (2) If the application is incomplete, HCFA notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information
- (3) After evaluating all relevant information, HCFA determines whether the entity's application meets the applicable requirements of §422.6.
- (b) Use of information from a prior contracting period. If an entity has failed to comply with the terms of a previous year's contract with HCFA under title XVIII of the Act as an HMO, competitive medical plan, health care prepayment plan, or M+C organization or an

entity has failed to complete a corrective action plan during the term of the contract, HCFA may deny an application based on the entity's failure to comply with that prior contract with HCFA even if the entity meets all of the current requirements.

(c) Notice of determination. HCFA notifies each entity that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) Approval of application. If HCFA approves the application, it gives written notice to the M+C organization, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If HCFA finds that the entity does not appear to meet the requirements of an M+C organization and appears to be able to meet those requirements within 60 days, HCFA gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding and may revise its application to remedy any defects HCFA identified.

- (f) Denial of application. If HCFA denies the application, it gives written notice to the M+C organization indicating—
- (1) That the M+C organization does not meet the contract requirements under part C of title XVIII of the Act;
- (2) The reasons why the M+C organization does not meet the contract requirements; and
- (3) The M+C organization's right to request reconsideration in accordance with the procedures specified in subpart N of this part.
- (g) Oversight of continuing compliance.
 (1) HCFA oversees an entity's continued compliance with the requirements for an M+C organization.
- (2) If an entity no longer meets those requirements, HCFA terminates the contract in accordance with § 422.510.

§ 422.10 Cost-sharing in enrollment-related costs.

(a) Basis and scope. This section implements that portion of section 1857 of

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the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that HCFA follows to assess the required fees on M+C plans offered by M+C organizations.

- (b) Purpose of assessment. Section 1857(e)(2) of the Act authorizes HCFA to charge and collect from each M+C plan offered by an M+C organization its pro rata share of fees for administering section 1851 of the Act, relating to dissemination of enrollment information; and section 4360 of the Omnibus Budget Reconciliation Act of 1990, relating to the health insurance counseling and assistance program.
- (c) Applicability. The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.
- (d) Collection of fees—(1) Timing of collection. HCFA collects the fees over nine consecutive months beginning with January of each fiscal year.
- (2) Amount to be collected. The aggregate amount of fees for a fiscal year is the lesser of the following:
- (i) The estimated costs to be incurred by HCFA in that fiscal year to carry out the activities described in paragraph (b) of this section.
- (ii) The amount authorized in the DHHS appropriation for the fiscal year.
- (e) Assessment methodology. (1) The amount assessed is a percentage of the total Medicare payments to each organization. HCFA determines the percentage rate using the following formula:

A times B divided by C where-

A is the total of the estimated January payments to all organizations subject to assessment;

B is the nine-month (January through September) assessment period; and

C is the total assessment amount authorized for the particular fiscal year in accordance with paragraph (d)(2) of this section.

(2) HCFA determines each organization's pro rata share of the annual fee on the basis of that organization's calculated monthly payment amount during the nine consecutive months beginning with January. HCFA calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in

HCFA's payment system on the first day of the month.

- (3) HCFA deducts the organization's fee from the amount of Federal funds otherwise payable to the organization for that month under the M+C program.
- (4) If assessments reach the amount authorized for the year before the end of September, HCFA discontinues assessment.
- (5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section or the fee percentage rate specified in paragraph (e), HCFA may adjust the assessment time period and the fee percentage amount.

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an M+C plan.

- (a) An individual is eligible to elect an M+C plan if he or she—
- (1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who is (or was) enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);
- (2) Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization offering an M+C plan in the service area or continuation area in which the individual resides may continue to be enrolled in the M+C organization as an M+C plan enrollee;
- (3) Resides in the service area of the plan, except that an individual who resides in a continuation area of an M+C plan while enrolled in a health plan offered by the M+C organization may continue to be enrolled in the M+C organization as an M+C plan enrollee;
- (4) Completes and signs an election form and gives information required for enrollment; and